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Dated: November 20, 2008 Signature: \_\_\_\_\_

(Rory P. Pfeiffer)

Docket No.: 101896-0366  
(DEP5181)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

Bryan S. Jones et al.

Application No.: 10/813,904

Filed: March 31, 2004

For: HEAD-TO-HEAD CONNECTOR SPINAL  
FIXATION SYSTEM

Confirmation No.: 5037

Art Unit: 3733

Examiner: A. Yang

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**COMMENTS FOR PRE-APPEAL BRIEF REVIEW**

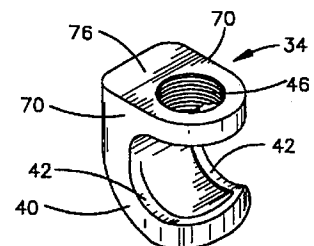
Dear Sir:

These comments are being filed concurrently with a Notice of Appeal and a Pre-Appeal Brief Request for Review. Claims 1, 4-35, 56, 57, and 59-63 are pending and stand rejected. Reconsideration is respectfully requested based on the legal and factual deficiencies of the current rejections.

***Rejections of Claims 1, 4-11, 15-20, 29, 56, and 60-63***

The Examiner rejects claims 1, 4-11, 15-20, 29, 56, and 60-63 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,397,363 to Gelbard ("Gelbard") in view of U.S. Patent No. 5,522,816 to Dinello et al. ("Dinello"). With respect to independent claims 1, 56, and 60, the Examiner relies on Gelbard to teach the claimed invention but admits that Gelbard does not disclose a connecting plate with a distal surface that *bears against a proximal terminal end surface of the opposed arms of the rod receiving portion of at least one of the bone anchors*. The Examiner relies on Dinello for this feature, arguing that modifying the Gelbard device in view of Dinello would lead to the claimed invention. Applicants disagree.

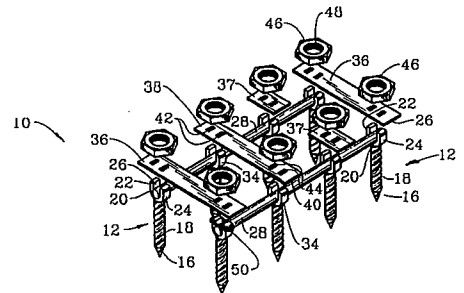
The rejection is factually deficient at least because neither Gelbard nor Dinello teach or suggest a device in which a distal surface of a connecting plate bears against a proximal terminal end surface of *opposed arms* of a bone anchor. The Examiner agrees that Gelbard lacks such a teaching. Dinello does not remedy this deficiency because Dinello teaches sitting a plate on top of a hook member (34) having a proximal flat surface (76), as shown in a reproduction of FIG. 3 of Dinello herein. Dinello simply does not teach or even suggest placing a plate on a proximal



**Fig.3**

terminal end surface *of opposed arms* of a bone anchor, and thus there is clearly no teaching to make the modification suggested by the Examiner. Instead, as explained below, the only teaching to make the modification is set forth in the present invention, and thus is based on impermissible hindsight.

Further, it is legally impermissible to modify the device of Gelbard to have a connecting plate that *bears against a proximal terminal end surface of the opposed arms of the anchors*. As illustrated in a partial reproduction of FIG. 1 of Gelbard herein, Gelbard is specifically directed to a plate (36) having *openings (42, 44) that receive opposed arms (22, 24) of a bone anchor (12) therethrough* to allow a nut (46) to be *screwed to the opposed arms (22, 24)* and secure the plate (36) to the anchor (12). The arms (22, 24) of the anchor (12) pass through plate (36) so that the plate (36) can be locked to the anchor (12) by way of the nut (46). The proposed modification, which would require the plate to *rest on top of the opposed arms (22, 24)*, changes the principle of operation of the Gelbard device. *See* page 2, line 24 to page 3, line 22 of the Response to Non-Final Office Action dated May 6, 2008, hereinafter “the Response.” In accordance with MPEP 2143.01(VI), if a proposed modification would change the principle of operation of the device being modified, the teachings of the combined references are not sufficient to render the claims *prima facie* obvious. The Examiner’s proposed modification clearly changes the principle of operation of the Gelbard device. *Passing the opposed arms through the plate* is a key feature of Gelbard, as evidenced by the fact that *each* embodiment of a plate (36, 60, 80, 90, 170, 242) includes such a configuration and substantial portions of the disclosure are directed to embodiments in which the openings rotate to accommodate situations that would have previously required screw removal and replacement. *See at least* Gelbard Col. 5, lines 10-45. In fact, as stated in the Summary of the Invention section of Gelbard:



*Unique* to this invention is that the screw is threaded *on the outer surface of the saddle* allowing the alignment rod to be securely fastened into the saddle by placement of the rod therein and the *fastening of a nut to the top of saddle*. Further, *unique* to this invention is the use of an elongated sagittal traverse support member that can *accommodate the saddle protrusion either in a fixed position or by use of a rotatable insert* that allows the cross member to be tightly fastened to the saddle in a variable alignment.

Col. 2, lines 10-19, *emphasis added*. Gelbard also notes that by threading a nut (46) directly to the top of the anchor (12), the need for movement of muscle during surgery is eliminated. *Id.* at lines 53-55. It is clear that configuring the plate so that the arms pass therethrough and a closure mechanism is screwed to the top of the arms to secure the plate were important and *unique* features of Gelbard’s invention that cannot be abandoned. The Examiner’s proposed modification, however, does just that because it would require the plate to *bear against* the proximal terminal surface of the arms rather than having the arms pass *through* the plate, as

specifically required by the teachings of Gelbard. The proposed modification would also eliminate the need for the nut (46), since the nut could no longer be threaded to the arms. Changing these principles of operation of the Gelbard device is legally impermissible.

The Examiner also fails to provide the requisite motivation necessary for making the proposed modification. In accordance with the procedures outlined by the MPEP in light of *KSR International Co. v. Teleflex Inc.* (“KSR”), there must be one or more clearly articulated reasons as to why the claimed invention would have been obvious to support any rejection under 35 U.S.C. §103.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) notes that the analysis supporting a rejection under 35 U.S.C. 103 *should be made explicit*. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there *must be some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval.)

MPEP § 2142, *emphasis added*. The Examiner fails to provide any explicit, articulated reasoning as to why a person of ordinary skill in the art would have been motivated to change the design of the Gelbard device. There is no reason why a person of ordinary skill in the art would change the design of the Gelbard device so that the arms of the anchor no longer pass through the plate. In fact, the modification would not simplify the device or provide a better construct as it would require additional parts resulting in a more complicated procedure. Gelbard’s anchor utilizes a single nut that both locks a spinal rod to the anchor and that locks the plate to the anchor. Dinello’s anchor, on the other hand, utilizes two separate locking mechanism: a set screw (48) to lock a spinal rod in the anchor, and a locking nut (74) that locks the plate to the anchor. Thus, modifying Gelbard to utilize Dinello’s locking mechanism would require an additional locking component, thus rendering the device more complicated and time consuming during application. No person having ordinary skill in the art would make such a change. The modification suggested by the Examiner would also require a significant reconstruction and redesign, including removing the openings for the arms, forming different sized openings in the plate to receive a set screw, and removing the threads on the opposed arms. The Examiner cannot reasonably suggest that all of these changes would be made despite the fact that there was no problem to solve and no suggestion or motivation to move away from the primary teachings of Gelbard, which require the arms to extend through the plate. Without clear, articulated reasoning to change the specific design of Gelbard, the rejection is legally deficient.

Not only does the Examiner fail to articulate a reason for making the proposed modification, the Examiner relies upon impermissible hindsight to modify the device of Gelbard to include a connecting plate having a distal surface that *bears against a proximal terminal end surface of the opposed arms* of the receiving portion of the bone anchor(s). *Id.* In accordance with MPEP § 2141.01(III), the Examiner must guard against impermissible hindsight that results from the knowledge of the invention of the present application and the Examiner may not “use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted). Gelbard specifically relies upon a design in which arms *pass through* the connecting plate, which is clearly different than the claimed design in which a distal surface of the connecting plate *bears against a proximal terminal end surface of the opposed arms* of the receiving portion of the bone anchor(s). As explained above, Dinello only teaches a hook member having a flat surface, not arms. To the extent that Dinello teaches “providing a connecting plate along a proximal terminal end surface of a rod engaging member” as the Examiner suggests, it certainly does not teach providing a plate along a proximal terminal end surface *of opposed arms*. In view of Dinello, a person of ordinary skill in the art would not bear the plate against the arms of the anchor of Gelbard. Rather, a person would eliminate the arms, at least because they were no longer needed to extend *through* the plate in the proposed modification, and instead would use a flat surface like the one disclosed in Dinello on the Gelbard anchors. It is only because of the instruction template provided by the claimed invention that the Examiner proposes the modification. Accordingly, even if it can be said that there was motivation to rely upon the teachings of Dinello to modify the Gelbard device, the proposed modification is legally and factually deficient because the modification would not have led to the plate bearing against the top surfaces *of the arms* of the anchor of Gelbard in view of Dinello.

The Examiner also clearly erred in rejecting independent claims 56 and 60 by arguing that one skilled in the art would have modified the device of Gelbard such that a set screw extends through a plate to threadingly engage the rod receiving portion. Gelbard is specifically directed to a closure mechanism (46) that is *screwed to the opposed arms* (22, 24) to secure the plate to the bone anchor. The proposed modification changes the principle of operation of the device of Gelbard at least because the closure mechanism would no longer be *screwed to the opposed arms*. Further, the Examiner fails to provide the necessary motivation for the modification, instead relying upon impermissible hindsight to use set screws as a closure mechanism that *extends through the connecting plate*. The Examiner provides no articulated reasoning why a person of ordinary skill in the art would modify Gelbard to eliminate the nut and instead insert a set screw through the connecting plate to serve as the closure mechanism. Without a clear motivation

to change the specific design of Gelbard, especially in view of the change to the principle of operation of the device of Gelbard that would result, the rejection is legally deficient.

Applicants respectfully request reconsideration of the current rejections of each of independent claims 1, 56, and 60, as well as claims 4-11, 15-20, 29, and 61-63 which depend therefrom, in light of the fact that the Examiner's current rejections are clearly deficient both factually and legally to make out a prima facie case of obviousness.

**Rejection of Claims 12-14, 21-28, 30-35, 57, and 59**

The Examiner rejects claims 12-14, 21-28, 30-35, 57, and 59 pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of Dinello and further in view of at least one of U.S. Publication No. 2004/0087949 to Bono et al. ("Bono"), U.S. Publication No. 2004/0186474 to Mathis et al. ("Mathis"), U.S. Patent No. 5,366,455 to Dove et al. ("Dove"), and U.S. Patent No. 6,355,038 to Pisharodi ("Pisharodi"). None of Bono, Mathis, Dove, and Pisharodi, either alone or in combination, remedy the deficiencies of the Examiner's proposed modifications of the Gelbard device in view of Dinello. In particular, none of the references teach or even suggest a device in which a distal surface of a connecting plate bears against a proximal terminal end surface *of opposed arms* of an anchor, and further, none of the references remedy the deficiencies related to changing the principle of operation of the Gelbard device, lacking motivation for the combination to be made, and requiring impermissible hindsight to arrive at the claimed invention.

Accordingly, Applicants respectfully request reconsideration of the current rejections of claims 12-14, 21-28, 30-35, 57, and 59 in light of the fact that the Examiner's current rejections are clearly deficient both legally and factually to make out a prima facie case of obviousness.

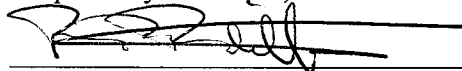
***Conclusion***

In view of the above remarks, Applicants submit that all claims are condition for allowance, and allowance thereof is respectfully requested.

Date: November 20, 2008

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Respectfully submitted,



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